



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/538,885

03/29/2006

Craig L. Nessler

01640421AA

8840

30743

7590

09/02/2008

WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

09/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,885	Applicant(s) NESSLER ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 13-19 are pending.
2. The restriction among the different enzymes in Group II is withdrawn, as art on all groups was found. Claims 13-19 are examined.
3. 35 USC 112, 6th paragraph, has been invoked for claim 15.
4. The objection to claims 14 and 15 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of Applicant's amendment of the claims.
5. The rejection of claims 13-15 and 20 under 35 U.S.C. 102(b) as being anticipated by Jain et al (2000, Molecular Biology 6:73-78) is withdrawn in favor of the new rejections below.
6. The rejection of claims 13-16, 19-20 under 35 U.S.C. 103(a) as obvious over Jain et al (2000, Molecular Biology 6:73-78) in view of Arner et al (2001, Biochem J. 360:313-320) is withdrawn in favor of the new rejections below.
7. The rejection of claims 13-16, 19-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the teachings in the art.
8. The rejection of claims 13-16, 19-20 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing endogenous Vitamin C by transforming plants with At-MIOX4, does not reasonably provide enablement for reducing TSNA's in tobacco with at least one gene in a Vitamin C biosynthetic pathway is withdrawn in light of the teachings in the art.

Claim Rejections - 35 USC § 112

9. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no disclosure in the specification to describe the means for enhancing transcription of said gene or genes. There is no description of the structure or materials perform the function in the “means for” limitation.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 13 is indefinite in its recitation of “TSNAs”. Abbreviations should be defined in the claim.

Claim 15 is indefinite in its recitation of “means for enhancing transcription of said gene or genes” as no associate structure is defined.

Claim Rejections - 35 USC § 103

12. Claims 13-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al (US 2004/0185562, filed March 2001) in view of Rundlöf et al (2000, J. Agric. Food. Chem. 48:4381-4388).

The claims are drawn to a method comprising air-curing a genetically engineered plant that is transformed with a gene in a vitamin C pathway and has increased endogenous levels of vitamin C, wherein the gene encodes myo-inositol oxygenase.

Schroeder et al teach a method of producing ascorbic acid in plants by expressing in them a gene encoding myo-inositol oxygenase (claim 90). Schroeder et al teach that these plants include tobacco (¶130). Because the plants express the protein, they have a means for enhancing transcription of said gene. Schroeder et al do not teach air curing the tobacco.

Rundlöf et al teach that ascorbic acid inhibits TSNA formation in air-cured tobacco plants (paragraph spanning the columns on pg 4387; Table 4).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to air cure the tobacco plants Schroeder et al as described in Rundlöf et al. One of ordinary skill in the art would have been motivated to do so because Rundlöf et al teaches that ascorbic acid inhibits formation of TSNA, which are undesirable, in air-cured tobacco plants. It would have been obvious to one of ordinary skill in the art to express more than one copy of the gene in the plants; one of ordinary skill in the art would have been motivated to do so to obtain higher levels of ascorbic acid in the plants. The pathway in which myo-inositol oxygenase works contains an L-gulonolactone oxidase enzyme.

Art Unit: 1638

13. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (2000, Molecular Breeding 6:73-78) in view of Rundlöf et al (2000, J. Agric. Food. Chem. 48:4381-4388).

The claims are drawn to a method comprising air-curing a genetically engineered plant that is transformed with a gene in a vitamin C pathway and has increased endogenous levels of vitamin C, wherein the gene encodes L-gulono- γ -lactone oxidase.

Jain et al teach tobacco plants transformed with a gene encoding rat L-gulono- γ -lactone oxidase; the plants have 7 times more ascorbic acid than non-transformed plants (pg 76, left column, paragraphs 1-2). The 35S promoter is the means for enhancing transcription of said gene (pg 76, left column, paragraph 1). Jain et al do not teach air curing the tobacco plants.

Rundlöf et al teach that ascorbic acid inhibits TSNA formation in air-cured tobacco plants (paragraph spanning the columns on pg 4387; Table 4).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to air cure the tobacco plants taught by Jain et al as described in Rundlöf et al. One of ordinary skill in the art would have been motivated to do so because Rundlöf et al teaches that ascorbic acid inhibits formation of TSNA, which are undesirable, in air-cured tobacco plants. It would have been obvious to one of ordinary skill in the art to express more than one copy of the gene in the plants; one of ordinary skill in the art would have been motivated to do so to obtain higher levels of ascorbic acid in the plants. The pathway in which L-gulono- γ -lactone oxidase works contains a myo-inositol oxygenase enzyme.

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al in view of Rundlöf et al as applied to claims 13-18 above, and further in view of Arner et al (2001, Biochem J. 360:313-320).

The claims are drawn to a method comprising air-curing a genetically engineered plant that is transformed with a gene in a vitamin C pathway and has increased endogenous levels of vitamin C, wherein the gene encodes myo-inositol oxygenase.

The teachings of Jain et al in view of Rundlöf et al are discussed above. Jain et al in view of Rundlöf et al do not teach a gene encoding myo-inositol oxygenase.

Arner et al teach a gene encoding myo-inositol oxygenase (Fig 3) and that myo-inositol oxygenase converts myo-inositol to D-glucuronate (Fig 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method comprising air-curing a genetically engineered plant that is transformed with a gene in a vitamin C pathway taught by Jain et al in view of Rundlöf et al to use the gene encoding myo-inositol oxygenase described in Arner et al as the gene in the pathway. One of ordinary skill in the art would have been motivated to do so because Arner et al teach that myo-inositol oxygenase converts myo-inositol to D-glucuronate (Fig 1), which Jain et al teach is one of the intermediates in the animal vitamin C biosynthetic pathway (Fig 1). Substitution of one enzyme in the pathway for another is an obvious design choice and an optimization of design parameters. Further, Jain et al suggests using one or more enzymes in the animal pathway (pg 73, right column, paragraph 2),

Art Unit: 1638

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

September 2, 2008

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638